IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL CASES IDENTIFIED IN EXHIBIT A TO UNDERLYING MOTION**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF DR. SALIL KHANDWALA

Defendant Ethicon Corp. ("Defendant"), as the proponent of the expert testimony, bears the substantial burden of establishing that expert Dr. Salil Khandwala, M.D. ("Dr. Khandwala") is sufficiently qualified and that the proffered testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Defendant has not satisfied this burden. Plaintiffs submit this Reply in support of their Motion to limit the opinions of Dr. Khandwala.[1]

ARGUMENT

1. **Dr. Khandwala lacks the requisite qualifications to opine on the adequacy of IFUs and patient brochures and any such opinions are unreliable.**

Dr. Khandwala's testimony and expert reports reveal his lack of qualifications with respect to the adequacy of the Instructions for Use (IFU), warnings, and patient brochures for the TVT, TVT-O, and TVT-S. *See* Pls.' Mot. Ex. B, General Expert Report (TVT, TVT-O) of Dr. Khandwala; Ex. C, General Expert Report (TVT-S) of Dr. Khandwala; Ex. D, Deposition of Dr.

[1] Plaintiffs also hereby adopt and incorporate by reference the *Daubert* reply filed with respect to Salil Khandwala, M.D. in Wave 1, [Dkt. 2240 (memorandum in support)], related to his opinions on the Prolift or Prolift+M devices, as well as the components Gynemesh PS and Ultrapro mesh, and respectfully request that the Court exclude Dr. Khandwala's testimony for the reasons expressed in the Wave 1 briefing.

Salil Khandwala. Dr. Khandwala candidly admitted at his deposition that "I do not know what Ethicon puts in and what they need to put in" the Instructions for Use. Ex. D, 177:9-10. He further testified to a complete lack of experience in drafting Instructions for Use or warnings. *Id.* at 158:24-159:12, 57:18-23. This testimony demonstrates that Dr. Khandwala lacks the most basic understanding of what an IFU should or should not include and, therefore, is not qualified to render an opinion as to the adequacy of the IFU or warnings for the TVT, TVT-O, and TVT-S.

Defendant's use of case law to support its assertion that an expert is qualified to opine on product labeling from a clinical perspective is off base. *See* Defs.' Opp. at 5-6. Dr. Khandwala's opinions go far beyond a mere application of his clinical experience to the labeling of the TVT-O, TVT, and TVT-S. Instead, Dr. Khandwala provides the sweeping opinion that he has reviewed the pertinent IFUs and, based on his expert review, can state that each is adequate. Ex. B at 32; Ex. C at 61. He further opines that the risks identified in the IFUs adequately describe the risks specific and unique to the TVT, TVT-O, and TVT-S and that the IFUs for each are adequate based on his review of IFUs for other products "from various medical device manufacturers." Ex. B at 34; Ex. C at 61-62. But, as Plaintiffs have shown, Dr. Khandwala testified that he lacks experience in product labels and warnings. Ex. D, 158:24-159:12, 57:18-23. Dr. Khandwala, therefore, is not qualified to render opinions on such topics.

Defendant seeks to equate Dr. Khandwala's testimony regarding the adequacy of the TVT, TVT-S, and TVT-O IFUs with that of Dr. Rosenzweig, who this Court determined was qualified to testify as to the adequacy of product warnings. Defs' Opp. at 6, *Huskey v. Ethicon*, 29 F. Supp. 3d 691 (S.D. W. Va. 2014). But, unlike Dr. Khandwala, Dr. Rosenzweig consulted on product warnings, including an IFU and patient brochure, and served on another company's scientific advisory committee that had worked on similar documents, which this Court credited

in concluding that Dr. Rosenzweig was qualified. *Huskey*, 29 F. Supp. 3d at 703-04. Dr. Khandwala can offer no such qualifications, and his opinion regarding the adequacy of the IFUs should, therefore, be excluded. *See Waltman v. Boston Sci. Corp.*, No. 2:12-cv-691, 2016 WL 3198322, at *17, *18, *21 (S.D. W. Va. June 8, 2016) (excluding experts as unqualified to render opinions on adequacy of DFU).

Defendant does not substantively address Dr. Khandwala's qualifications to opine on patient brochures. But Dr. Khandwala's lack of qualifications to opine on IFUs also applies to the patient brochures for the TVT, TVT-O, and TVT-S. As he did when asked about his qualifications related to IFUs, Dr. Khandwala stated at his deposition that he has no experience creating or drafting patient brochures. Ex. D at 159:13-18.

Dr. Khandwala's opinions regarding the adequacy of the IFUs and patient brochures lack any reliable scientific methodology. Despite Dr. Khandwala's admission that he is not a regulatory expert, Defendant inexplicably argues that Dr. Khandwala's opinion is reliable, in part, due to his reliance on FDA regulations and an FDA memo and FDA statement. Ex. D at 57:15-17, 177:8-9 ("I'm not a regulatory person as I told you."); Defs' Opp. at 8. But, as this Court has repeatedly held, opinions regarding product labeling derived from FDA requirements are unhelpful and would likely cause jury confusion. *See, e.g., Carlson v. Boston Sci. Corp.*, No. 2:13-cv-05475, 2015 WL 1931311, at *26 (S.D. W. Va. Apr. 28, 2015). Further, Defendant's attempt to refute Plaintiffs' citation to *Tyree v. Boston Sci. Corp.* and *Waltman v. Boston Sci. Corp.* fails because each case, as cited, focuses on the expert's qualification, not his methodology. Dr. Khandwala's methodology remains unreliable and his opinions related to IFUs, warnings, and patient brochures should be excluded.

2. Dr. Khandwala should be excluded from offering opinions concerning biomaterials issues, including biocompatibility, degradation, particle loss, contraction, shrinkage, and porosity.

Dr. Khandwala is not qualified to opine on biomaterial issues, including biocompatibility, degradation, particle loss, contraction, shrinkage, and porosity. First, Dr. Khandwala lacks basic, first-hand knowledge of these topics. Dr. Khandwala acknowledged, at his deposition, very limited experience in removal—or even partial removal—of polypropylene mesh. Ex. D, 147:2-148:14.

Defendant incorrectly asserts that Dr. Khandwala shares the same experience and qualifications to form an opinion as doctors found by this Court to be qualified on this topic. *See* Defs.' Opp. at 11; *Huskey*, 29 F. Supp. 3d at 706-07 (Dr. Rosenzweig offered opinion based on more than 200 surgeries involving complications related to synthetic mesh, including removal of numerous TVT devices); *Trevino v. Boston Sci. Corp.*, No. 2:13-CV-01617, 2016 WL 2939521, at *5 (S.D. W. Va. May 19, 2016) (Dr. Galloway's opinion based on clinical observations from performing hundreds of revisions and removal procedures involving mesh). In fact, Dr. Khandwala testified that he has removed polypropylene mesh on approximately 25 occasions and only seven of those were related directly to polypropylene mesh used in stress urinary incontinence procedures (*e.g.*, the TVT, TVT-O, or the TVT-S). *See* Ex. D, 147:2-14. Unlike Drs. Rosenzweig and Galloway, Dr. Khandwala has had very little opportunity to form an opinion based on clinical experience because he has so infrequently been involved in the removal of mesh. Further, Dr. Khandwala is not qualified to opine on degradation because he admittedly doesn't believe it exists and also has never tested mesh for degradation.

> Q: Okay. And you haven't tested any mesh that you have removed from patients for degradation, have you?
>
> A: I don't believe the mesh degrades, but I have not done any of that.

> Q: So you haven't done any testing on that?
>
> A: No.

See id. at 141:15-20. Additionally, Dr. Khandwala has not tested explanted mesh to analyze it for shrinkage.

> Q: And with respect to slings specifically, you haven't done any studies on the mesh itself once it's been removed, even partially removed, in terms of shrinkage of the mesh or any alterations to the biomechanical properties of that mesh?
>
> A: I don't know how one can do shrinkage assessments in the lab, but biomechanical, I have not done any.

Id. at 144:22-145:4. Additionally, Dr. Khandwala has not published on the topic of degradation nor has he studied mesh explanted by others. *Id.* at 66:23-67:5, 148:12-14.

Dr. Khandwala's opinions regarding biocompatibility, degradation, particle loss, contraction, shrinkage, and porosity remain unreliable and unhelpful to a jury. Dr. Khandwala bases his opinion on not seeing "any migrating particles or mesh that was degraded based on an observation at surgery." Ex. B at 36; Ex. C at 67. But he also does not test mesh for degradation or change in mesh consistency, which does not satisfy the threshold of reliability. For example, Dr. Khandwala testified:

> Q: And you have not analyzed any of the mesh material that has been removed from women in terms of any degradation or change in consistency of that mesh from a pathologic point of view, have you?
>
> A: I have not analyzed mesh.

Ex. D at 97:16-20; *see also id.* at 141:15-20. Additionally, Dr. Khandwala has not analyzed mesh for shrinkage. *Id.* at 144:22-145:4 ("I don't know how one can do shrinkage assessments in the lab, but biomechanical, I have not done any."). Dr. Khandwala's clinical observations related to biomaterials issues are based on the kind of unscientific examination that have

routinely been excluded by this Court. *See, e.g.*, *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 554 (S.D. W. Va. 2014) (excluding opinions regarding explanted mesh when opinions not derived using "scientific methods"). Therefore, his opinions on biomaterials issues should be excluded.

3. Dr. Khandwala lacks the requisite qualifications to opine on the design of the TVT, TVT-O, and TVT-S and any opinions offered are unreliable.

Dr. Khandwala lacks any experience in the design of the TVT, TVT-O, and TVT-S or any other relevant device and is, therefore, not qualified to testify on design issues. Dr. Khandwala's deposition testimony demonstrated his lack of relevant experience. *See* Ex. D, 156:2-8, 157:5-11, 157:21-23.

Defendant conflates design technique with device design in a failed attempt to demonstrate pertinent experience that Dr. Khandwala does not have. *See* Defs.' Opp. at 13. Dr. Both the drawings and patent Defendants reference concern technique, *not* the device, as Dr. Khandwala testified to at his deposition. Ex. D, 68:20-24, 154:13-15. Additional testimony reveals that Dr. Khandwala lacks any experience designing any of the relevant devices.

> Q: Okay. And with respect to the design of Ethicon's synthetic midurethral sling, you did not participate in the design of those products, is that correct?
>
> A: That is correct.
>
> Q: And you did not participate in the design controls with respect to those products? That is correct.

Id. at 156:2-:8. Dr. Khandwala's complete lack of experience relating to the design of the TVT, TVT-O, and TVT-S—or any mesh device—renders his opinions on design inadmissible. *See Tyree*, 54 F. Supp. 3d at 581 (excluding expert's opinion on design of Obtryx after expert admitted he lacked experience with sling design); *see also Robbins v. Boston Sci. Corp.*, No.

2:12-CV-01413, 2016 WL 3189248, at *22 (S.D.W. Va. June 7, 2016) (excluding expert's opinion regarding mesh design where expert testified he had not designed any POP products and rejecting argument that expert had sufficient experience with pelvic floor kits to opine as to device design).

Defendant attempts to use *Huskey v. Ethicon* as support for its assertion that Dr. Khandwala is qualified to opine on the design of TVT products. Defs.' Opp. at 13 (citing *Huskey*, 29 F. Supp. 3d at 721). But, in *Huskey*, this Court considered the qualifications of a doctor to opine regarding mesh-related complications, *not* TVT design, when it credited the doctor's knowledge of what other physicians knew regarding the standard of care for designing a mesh product and warning about its potential risks. *Huskey*, 29 F. Supp. 3d at 721.

Defendant does not refute Plaintiffs' argument that Dr. Khandwala's methodology in forming his opinions on the design of the TVT, TVT-O, and TVT-S are unreliable and, therefore, these opinions should be excluded. *See* Pls.' Mem. at 17-18. Because Defendant provided no opposition to this argument and for the reasons provided in Plaintiffs' Motion, Dr. Khandwala's design opinions should be excluded.

Finally, Defendant does not contest Plaintiffs' argument to exclude Dr. Khandwala's opinions on FDA regulations, FDA clearance, and compliance with the same. Therefore, for the reasons provided in Plaintiffs' Motion, Dr. Khandwala's opinions on FDA regulations, FDA clearance, and compliance with the same should be excluded.

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Khandwala is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering Dr.

Khandwala's lack of qualifications for the opinions proffered and the inherent unreliability of Dr. Khandwala's opinions, Ethicon cannot carry this burden and Dr. Khandwala's testimony should be limited as set forth herein.

Dated: August 18, 2016

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By: /s/Yvonne M. Flaherty

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CERTIFICATE OF SERVICE

I hereby certify that on August 18, 2016, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/ Yvonne M. Flaherty